move to bring to a close debate on the pending committee substitute amendment to S. 534, the solid waste disposal bill.

John H. Chafee, Bob Dole, Bob Smith, Jim Jeffords, Hank Brown, Kit Bond, Orrin Hatch, Spencer Abraham, Jon Kyl, Larry E. Craig, Kay Bailey Hutchison, Trent Lott, R.F. Bennett, Pete V. Domenici, Dirk Kempthorne, Jesse Helms.

MORNING BUSINESS

(During today's session of the Senate, the following morning business was transacted:)

PRODUCT LIABILITY FAIRNESS ACT

Mr. DODD. Mr. President, today the Senate passed the Product Liability Fairness Act, which I have cosponsored, by an overwhelming vote of 61–37. For those of us who have been working on this issue for a long time—my involvement dates back to 1985—this is an historic day. With passage of this balanced measure, we have taken a huge step toward improving the product liability system for everyone—for the injured people who need fast and fair compensation, for consumers who need quality products to choose from, for those American businesses who are at the cutting edge of international competition, and for workers who depend on a strong economy to support their families.

I commend Senator ROCKEFELLER and Senator GORTON, and their staffs, for their heroic efforts on this measure. From drafting the legislation, to skillfully guiding it through a lengthy debate on the Senate floor, they have worked extremely effectively. Their success is reflected in the broad bipartisan coalition that supported the bill.

I also commend Senator LIEBERMAN, my colleague from my home State of Connecticut. He authored an important section on biomaterials. That provision is designed to ensure that manufacturers of life-saving and life-enhancing medical devices have access to raw materials. In recent years, the supply of raw materials has been threatened by litigation. This is a critical problem, and I commend Senator LIEBERMAN for crafting a promising solution.

Of course, like any compromise, this bill will not please everyone in all respects. I had drafted, for example, an amendment providing a different approach to punitive damages. under my amendment, the jury would determine whether punitive damages are appropriate, and the judge, guided by certain factors, would determine the amount. That procedure, in my view, offers a better approach to punitive damages than one which provides limits, or caps. Senators ROCKEFELLER and GORTON incorporated some aspects of my proposal in the final provision, and I appreciate their efforts on this difficult issue.

The final version of this bill does not contain a provision that I have supported in the past—the Government standards defense. One aspects of that defense, related to approval of drugs and medical devices by the Food and Drug Administration, was passed by voice vote in the House and will, I understand, be considered in conference. I ask unanimous consent that a number of letters supporting this provision be printed in the RECORD at the end of my remarks. As these letters point out, inappropriate punitive damages have convinced many corporate researchers to avoid the search for safer and more effective drugs.

Once again, I commend my colleagues, particularly Senators ROCKEFELLER and GORTON, for their bipartisan efforts on the Product Liability Fairness Act.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Washington, DC, April 25, 1995.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC

DEAR SENATOR DODD: As a physician volunteer, I treat AIDS patients at the Whitman-Walker Clinic. The suffering that I see—and the threat of an ever-wider epidemic—convince me that the greatest gift anyone could give to society would be an AIDS vaccine. If I were the chairman of a philanthropic foundation, I would invest every dollar in vaccine research.

However, if I were CEO of a pharmaceutical company, knowing that the investment in my company represented the retirement and college savings of many of my stockholders, I wouldn't touch AIDS vaccine research with a ten-foot pole—until the liability issue has been successfully addressed.

Even the safest, most widely accepted vaccines entail risks—and potentially bankrupting liability burdens. Childhood vaccines are available in adequate supply only because Congress passed the Childhood Vaccine Compensation Act. This came about only because several manufacturers got out of the business of manufacturing childhood vaccines due to liability concerns—raising fears of a dangerous scarcity.

In 1975, a man who got polio after changing his baby's diaper sued the manufacturer of the Sabin polio vaccine, which the baby had received. The risk of polio transmission was known, but small—about 1 in 1 million. Nevertheless, the jury awarded punitive damages. The award was later reversed, but only by the narrowest possible margin. The very fact that such a widely acclaimed health advance could expose a manufacturer to punitive damages would certainly give pause to any manufacturer considering research on an AIDS vaccine—which entails special liability risks.

With a preventive AIDS vaccine, people who are vaccinated will probably turn HIV positive—with all the social stigma and threat of job loss or insurance loss that this involves. There is a risk that a very small number of people will get AIDS from the vaccine. Additionally, there is the risk that the vaccine won't ''take'' in all cases and that some people who think they are protected may engage in risky behavior and come down with AIDS. All of these eventualities could result in lawsuits.

In the case of therapeutic vaccines for people who already have the disease, it would be very difficult to distinguish the symptoms of AIDS from any side-effects of the vaccine. And people with AIDS, prodded by unscrupulous lawyers, might easily be tempted to sue vaccine manufacturers.

Unless the liability threat is alleviated—at least by exempting manufacturers of FDA-approved products from punitive damages—developing an AIDS vaccine is decidedly a ''no-win'' proposition. This is outrageous, unfair, tragic—but true.

Sincerely,

JOHN D. SIEGFRIED, M.D.

MAY 2, 1995.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: We are writing to ask that you vote in favor of a proposal that we believe will have a positive effect on research and development of new medicines and medical devices. American innovation is in trouble in the courts particularly in the high risk areas of reproductive health. Liability fears have caused the withdrawal of new drugs and medical devices that the Food and Drug Administration (FDA) considers safe and effective. We understand that when S. 565, the ''Product Liability Fairness Act of 1995'' is considered on the Senate floor, an amendment will be offered that would prevent juries from second-guessing the FDA's scientific decisions that a drug is safe insofar as punitive damages are concerned.

The proposed FDA-approval defense to punitive damages would establish a defense to punitive damages in tort actions involving drugs or devices approved by the FDA and subject to FDA regulation. The defense would apply only to punitive damages, and would not be available to a manufacturer that has withheld or misrepresented information to the FDA, including all required post-approval disclosure of unexpected adverse effects.

In the past twenty years, most companies have halted U.S. research on contraceptives and drugs to combat infertility and morning sickness. As a case in point, Bendectin, a morning-sickness drug, was removed from the market by its manufacturer in 1984 after more than 2,000 lawsuits were filed claiming it caused birth defects. Merrell Dow has spent over $100 million defending those suits and is still doing so. Even though almost every court which has looked at the issue has determined that there is no scientific evidence to support the contention that the drug causes birth defects, and even though Bendectin is still approved by the FDA for use in pregnancy, no manufacturer will risk making a morning sickness drug.

The 1970s brought more litigation over oral contraceptives than any other drug. In the early 1970s, there were 13 companies doing research and development on contraceptives. Eight of these were American. Today there are only two major U.S. companies doing such research. In 1990, a distinguished panel of scientists put together by the National Academy of Sciences noted that due to fear of lawsuits, the United States is decades behind Europe and other countries in the contraceptive choices it offers women.

In early 1994, because it had spent tens of millions of dollars defending against suits by people claiming injury from tempero-mandibular joint implants, DuPont announced it would no longer make polymers available to the medical device industry in the United States. These polymers are used in artificial hearts, pacemakers, catheters, hip and knee prostheses, and a host of other implantable devices. We have not even begun to feel the full impact of that decision.

The Senate is taking advantage of an unprecedented opportunity to fix a flawed product liability system. We ask that you include

a reform that will encourage the development of better medical products without impairing the ability of people who are injured from recovering just compensation.

Sincerely,

NANCY SANDER,
Allergy and Asthma Network/Mothers of Asthmatics, Fairfax, Virginia.
PATRICIA TOMPKINS,
National Black Nurses' Association, Washington, DC.
DOROTHY I. HEIGH,
National Council of Negro Women, Inc., Washington, DC.
ADELE BAKER,
Wright, Robinson, McCammon, Osthimer and Taturn, Washington, DC.
SUSAN WALDEN,
Renaissance Women Foundation, Washington, DC.

NATIONAL FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOCIATION,
Washington, DC, May 1, 1995.

DEAR SENATOR: As the Senate considers S. 565, ''The Product Liability Fairness Act of 1995,'' we urge you to support a provision known as the FDA defense. With the FDA defense, companies would not be held liable for punitive damages in a lawsuit if the drug or medical device involved received pre-market approval from the FDA, and if the company fully complied with the FDA's rigorous requirements, which include specifying the warnings that companies must provide about their products and furnishing post-market reports on adverse reactions.

As an organization dedicated to expanding medical research and increasing access to products that can improve women's reproductive health, we know firsthand the extent to which the current liability system is impeding these important goals. In 1990, a distinguished panel of scientists put together by the National Academy of Sciences noted that due to U.S. Pharmaceutical companies fear of lawsuits, the United States is decades behind Europe and other countries in the contraceptive choices it offers women. An FDA defense would begin to turn the tide on this disturbing trend by encouraging research and development of products women need without impairing the ability of women who are injured by drugs and medical devices to recover just compensation.

We are deeply distressed that opponents of reform are mounting a fear-based campaign directed at women as their strategy to block change. A great deal of misinformation has been circulated concerning the impact of the FDA defense on women. We certainly recognize that women have had a painful history with medical products, such as DES and the Dalkon Shield, which have caused tragic injuries to women and their children. Opponents of an FDA defense are mistaken, however, in claiming this provision would have prevented plaintiffs from collecting punitive damages in these cases. In fact, the Dalkon Shield was on the market before the Medical Devices Amendment was adopted in 1976, and thus, was never approved by the FDA. As for DES, various manufacturers involved are alleged to have defrauded or withheld information from the FDA, and therefore would not be covered by the FDA defense.

The FDA defense would allow plaintiffs to obtain full compensatory damages and non-economic damages, including medical costs, lost wages, loss of functioning, and pain and suffering. We would not support the FDA defense if limited a plaintiff's ability to obtain full compensatory and non-economic damages in any manner. The FDA defense would limit only punitive damages. Also, the FDA defense would not be available to any company that is found to have lied or withheld information from the FDA or otherwise failed to comply with FDA rules.

The FDA defense is crucial given the current legal climate. A quick review of recent events clearly points out the impact of current policies. During the 1970s, there were 13 companies doing research and development on contraceptives. Eight of these companies were American. Today, only two American companies continue to conduct such research.

Given the current legal climate, it is easy to understand why companies are increasingly reluctant to make available products, despite their known therapeutic value. Two cases in point:

Bendectin, a morning sickness drug that was taken by over 30 million American women, was removed from the market by its manufacturer in 1984, after more than 2,000 lawsuits were filled claiming it caused birth defects. The manufacturer has spent over $100 million defending those lawsuits and is still doing so. Even though almost every court that has looked at the issue has determined there is no scientific evidence to support the contention that the drug causes birth defects, and even though Bendectin is still approved by the FDA for use during pregnancy, no other manufacturer will risk making a morning sickness drug.

Norplant, one of the most significant contraceptive developments of the past 20 yeas in the United States, was approved by the FDA in 1990. It is now the target of numerous cookie cutter, mass-produced class action lawsuits fueled by sensationalism and slick advertising directed at women. Despite the fact that Norplant continues to be supported by the medical community—as recently as a March 1995 endorsement by the American Society for Reproductive Medicine—many women have been driven by unwarranted fears away from a safe and effective contraceptive product.

Punitive damages are meant to punish willful, flagrant, malicious or grossly illegal behavior. A company that has compiled in good faith with the FDA's regulations cannot be guilty of such behavior and should not be threatened with punitive damages. Nor should juries be permitted to second-guess the expert judgment of the FDA on whether the benefits of a drug outweigh the risks.

Increasingly, the legitimate concerns for the health and welfare of American women are being sidelined in the pursuit of large financial settlements. It is our view that inclusion of a FDA defense, similar to the one included in the House-passed product liability bill, would provide a much needed incentive for increased investment in women's health research and technologies. We believe this is a measured response and we urge you to adopt an FDA defense in any final product liability legislation.

Sincerely,

JUDITH M. DESARNO,
President/CEO, National Family Planning and Reproductive Health Association.
PHYLLIS GREENBERGER,
Executive Director, Society of the Advancement of Women's Health Research.
DENNIS BARBOUR, J.D.
President, Association of Reproductive Health Professionals.
LINDA BARNES BOLTON, DR. P.H., R.N, FAAN,
President, National Black Nurses' Association, Inc.
SUSAN WYSOCKI, RNC, NP,
President, National Association of Nurse Practitioners in Reproductive Health.

MAY 1, 1995.

HON. CHRISTOPHER J. DODD,
SR–444 Russell Senate Office Building, Washington, DC.

DEAR SENATOR DODD: We have been asked to convey our views with regard to an amendment to H.R. 956, the Product Liability Fairness Act, to establish a defense to punitive damages for FDA-approved drugs and devices. Each of the undersigned has served at some time as Chief Counsel to the Food and Drug Administration. Each of us, in our current professional capacities, advises firms engaged in the manufacture of drugs and devices. However, the views expressed in this letter reflect our shared personal judgment.

The proposed defense to punitive damages for the marketing of medical products that meet applicable federal regulatory requirements makes eminent sense as a matter of public policy and can be expected to facilitate the development and continued availability of important products to treat and prevent serious disease and to address other significant health concerns. We describe below FDA's philosophy of new drug regulation and its powers in this area, which, we believe, strongly support the defense.

FDA exercises sweeping authority over the development, manufacture, and marketing of pharmaceuticals. Indeed, no other industry in this country is subject to such a comprehensive regulatory scheme. Pursuant to its statutory mandate, FDA requires premarket approval of all new drugs. A new drug may not be approved unless it has been shown to be safe and effective under the conditions of use described in its labeling.

In making their approval decisions, FDA physicians and scientists employ a risk-benefit standard. This standard recognizes that all drugs have unavoidable risks, some of them very serious. Therefore, FDA allows drugs onto the market only when the benefits from using a drug outweigh those risks. A drug's labeling is an important factor in making the approval decision. Once a drug is available, the treating physician, apprised of the recognized significant risks of a drug, can make an informed decision whether a drug is appropriate for use in a particular patient.

Inevitably, not all of the risks from a drug can be discovered prior to approval. While manufacturers are required to conduct extensive clinical trials, often in thousands of patients, some adverse events are so rare that they emerge only after a drug is in widespread use after approval. FDA therefore requires manufacturers to report all adverse events to the agency. The most serious of these must be reported within 15 days. FDA and the Justice Department have vigorously enforced the adverse event reporting requirements through a series of widely publicized criminal prosecutions.

FDA has the power to act swiftly and decisively when postmarket surveillance does identify a safety issue. The Secretary of Health and Human Services can immediately suspend approval of a drug that poses an imminent hazard, prior even to granting the manufacturer a hearing. FDA also can compel labeling changes to incorporate new safety information. As a practical matter, formal action under any of these authorities is rarely necessary because, in our experience, companies generally comply voluntarily with agency requests.

With this context, the desirability of the punitive damages defense is readily apparent. Where manufacturers have complied with all of FDA's approval, labeling, and safety reporting requirements, they should not be open to punishment through the imposition of punitive damages. This defense does nothing to restrict the availability of

compensatory damages. Injured persons will still be made whole for their losses under the law. And they will even be able to recover punitive damages in cases where their injuries were caused by violations of FDA regulations. The defense simply recognizes—as a clear rule—that manufacturers who comply with FDA's comprehensive regulatory process do not manifest the type of willful misconduct that could merit punitive damages.

While we recognize that the imposition of punitive damages is a comparatively rare (but by no means unknown) event, the threat of punitive damage awards skews the entire litigation process and, with it, the process for developing new drugs and making them available to the public. Pharmaceutical manufacturers have withdrawn beneficial products from the market and have ceased promising research because of this threat. Congress is now in the position to remove this obstacle and thereby to make a genuine contribution to the public health. We therefore urge you to support the FDA approval amendment to H.R. 956.

Sincerely,

THOMAS SCARLETT,
Hyman Phelps & McNamara, Chief Counsel—1981–89.

NANCY L. BUC,
Buc Levitt & Beardsley, Chief Counsel—1980–81.

RICHARD A. MERRILL,
Covington & Burling, Chief Counsel—1975–77.

RICHARD M. COOPER,
Williams & Connolly, Chief Counsel—1977–79.

PETER BARTON HUTT,
Covington & Burling, Chief Counsel—1971–75.

CONGRATULATING SENATOR DOLE ON THE EISENHOWER LEADERSHIP PRIZE

Mrs. KASSEBAUM. Mr. President, last night my colleague from Kansas, Senator DOLE, received the prestigious Eisenhower Leadership Prize in recognition of his distinguished service to the United States. I have long admired Senator DOLE for his leadership and dedicated service and am pleased that the Eisenhower World Affairs Institute and Gettysburg College recognized him with such a high honor.

This prize is made all the more notable because Dwight D. Eisenhower, the award's namesake, is a fellow Kansan and Senator DOLE's hero. I add my voice to the many who congratulate him on this honor and ask unanimous consent that the remarks Senator DOLE gave last night be printed in the RECORD.

There being no objection, the remarks were ordered to be printed in the RECORD, as follows:

I want to thank the Trustees of The Eisenhower World Affairs Institute and Gettysburg College for this honor.

I am truly humbled to receive this award. And I thank the Awards Committee for dipping down in the military ranks. The first Leadership Prize went to General Scowcroft. The second to General Colin Powell. Last year you honored Major Lloyd Bentsen. And this year, you're down to Lieutenant Bob Dole. I guess there's still hope for all you Privates out there.

A special word of thanks to my colleagues from the 10th Mountain Division who joins us this evening. I've always wondered why they assigned a kid from the plains of Kansas to the 10th Mountain Division. But I've never wondered about the men I served beside. You are all heroes in my book.

A few years back, the 10th Mountain veterans formed a national association. Over the years, there have been five Presidents of the Association, and I am honored that all five are here this evening. At least they got to be President of something.

I am also honored by the presence of many friends and colleagues of President Eisenhower and of several members of the Eisenhower family.

I have been privileged to get to know John on several occasions—including the Eisenhower Centennial in Abilene in 1990, and a few years ago in the Capitol when we unveiled the sign which marks the Eisenhower Interstate Highway System.

Elizabeth and I are very proud to call David and Julie Eisenhower our friends. We've also had the pleasure of meeting their children, and can tell you that David and Julie are as good as parents as they are authors.

And Mary Eisenhower Atwater was the one who came to my office last year to inform me of my selection as the recipient of this prize. The only promise I had to make to her was that my acceptance remarks would be brief.

In fact, I am tempted to do this evening what Ike did one evening when he was President of Columbia University. At the end of a long evening of speeches, Eisenhower's turn came. After being introduced, he stood up and reminded his audience that every speech, written or otherwise, had to have a punctuation. He said, ''Tonight, I am the punctuation. I am the period.'' And he sat down. He later said that was one of the most popular speeches he ever gave.

It is a bit intimidating to talk about President Eisenhower and his legacy before family members and friends and who knew him much better than I.

I can say, however, that, like countless Kansans and countless Americans, I not only ''liked Ike,'' I regarded him as a hero. I will never forget the first time I saw him. It was the spring of 1952. I had just finished law school, and was serving in the Kansas House of Representatives. General Eisenhower had come home to Abilene to officially launch his Presidential campaign, and I was in the rain-soaked audience that greeted him.

That campaign was, of course, wildly successful. And I took it as a good omen that my official announcement in Topeka on April 10 had to be moved indoors because of rain.

I did have the privilege of meeting my hero on several occasions during his lifetime, but the truth is I knew him no better than the countless soldiers who called him our general, and the millions of Americans who called him our President.

Eisenhower succeeded as a soldier and as a President for many reasons. Intelligence. Courage. Honesty. Leadership. The ability to place the right people in the right spots. These were all qualities Ike possessed.

But as I look at the Eisenhower statue in the reception area of my Capitol office, or the painting of Ike that hangs behind my desk, one word often comes to mind. And that word is ''Trust.''

Ike inspired trust as no leader has before or since. Millions of Americans may have voted for Adlai Stevenson in 1952 and 1956, but everyone trusted President Eisenhower to do what was best for America.

And there's a simple reason why America's citizens trusted Ike. And that's because he trusted America's citizens. Don't get me wrong. President Eisenhower believed in government—our Interstate Highway System is proof of that. But, moreover, Ike believed in citizens. He believed in the wisdom of the American people.

When Ike looked at America's people he saw himself. According to David Eisenhower, the title that meant the most to his grandfather was not ''Supreme Commander,'' or ''President;'' rather it was the simple title that all Americans share: The title of ''citizen.''

And David reminded me of a speech Ike made in London the month after VE Day. Ike said, ''To preserve his freedom of worship, his equality before law, his liberty to speak and act as he sees fit, subject only to provisions that he trespass not upon similar rights of others—a Londoner will fight. So will a citizen of Abilene.''

Throughout World War II, Ike saw himself as someone who would do what any American citizen would do when freedom was at risk. And throughout his Presidency, Ike spoke of how all of us shared with him the responsibility of guiding our country.

As Ike said in his first Inaugural address, ''We are summoned to act in wisdom and in conscience, to work with industry, to teach with persuasion, to preach with conviction, to weigh our every deed with care and with compassion. For this truth must be clear before us: Whatever America hopes to bring to pass in the world must first come to pass in the heart of America.''

What do those words mean in the America of 1995? I believe they mean we should rededicate ourselves to remembering the duties of citizenship: To keep informed and to become involved in the decisions that affect the life and future of all the citizens of our country.

And they also mean that government should trust the American people with decisions that matter most—the decisions that affect their families and their businesses.

To be sure, the 1950's weren't perfect. And as we look to the 21st century, we should not seek to return to those times. But what I hope America can return to is a relationship of trust between the people and their government. And if that's to happen, then we must rein in the federal government. It's too big, too intrusive, and makes too many decisions. I carry a copy of the 10th Amendment with me wherever I go. It's only 28 words long. And it basically states that all powers not specifically delegated to the federal government should be given to the states, and to the people. Dusting off that amendment, and restoring it to its rightful place in the Constitution is my mandate as Majority Leader, and I like to think that it's a mandate that Ike would have heartily endorsed.

Perhaps Ike said it best when he responded to those who were urging bigger and bigger government, all in the name of providing Americans with security.

''If all that Americans want is security, they can go to prison,'' Ike said. ''They'll have enough to eat, a bed, and a roof over their heads.

But he went on to say that citizens want more than security. We also want freedom. We want dignity. We want control of our lives. We want our government to trust us. And the lesson that Ike taught us is that if the American people believe our government trusts us, then we will trust our government in return.

Americans also trusted Ike because he trusted us with the truth. As Supreme Commander, Ike never hid the truth from his soldiers. If a mission was dangerous * * * if some wouldn't be coming home, then Ike laid it on the line. And, with his Kansas candor, he spoke about issues that many in Washington today shy away from. One of those was the federal budget.